Column E Explanation QA 1752, FY12

1. Registration Number: 84-F-0001

2. Number of animals used in this study during this reporting period:

Of the 17 house mice exposed, 7 were determined to have experienced more than momentary or slight pain or distress.
Of the 14 voles exposed, 7 were determined to have experienced more than momentary or slight pain or distress.
Of the 22 roof rats exposed, 8 were determined to have experienced more than momentary or slight pain or distress

3. Species (common name) of animals used in study:

House mouse
Voles
Roof rat

4. Explain procedure producing pain and/or distress:

Animals were exposed to an experimental toxicant in order to establish an LD 50 for this developmental toxicant in each species.

5. Provide scientific justification why pain or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

Sedatives, analgesics, or anesthetics could not be used because the animal must be functioning normally (metabolically and physiologically) when exposed so its efficacy can be determined under more or less normal conditions. Other substances in the animals' systems could confound the results of the study and lead to a false determination of the LD50 of this compound. Euthanasia of animals was allowed by the protocol for animals determined to be experiencing more than momentary or slight pain or distress.

6. What, if any federal regulations require this procedure?

Although no regulations specifically required this study, the data could be used for registration purposes and the study was conducted in accordance with current guidance from regulatory authorities.

Agency: US Environmental Protection Agency

CFR: 40 CFR Chapter 1, Part 158: Data Requirements for Registration of Pesticide Products.

Also: U.S. EPA 1996. Ecological Effects Test Guidelines: Wild Mammal Acute Toxicity. OPPTS 850.2400 and OPP Pesticide Assessment Subdivision G: Product Performance. Section 96-12: Rodentcides on Farm and Rangeland.

Column E Explanation QA 1781, FY12

1. Registration Number: 84-F-0001

2. Number of animals used in this study during this reporting period:

Of the 70 voles exposed, 29 were determined to have experienced more than momentary or slight pain or distress.

3. Species (common name) of animals used in study:

Voles

4. Explain procedure producing pain and/or distress:

Animals were exposed to a formulation of known toxicant that contained substances that were designed to increase acceptance. The concentration of the toxicant was reduced to minimize adverse effects.

5. Provide scientific justification why pain or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

Sedatives, analgesics, or anesthetics could not be used because the animal must be functioning normally (metabolically and physiologically) when exposed so formulation efficacy can be determined under more or less normal conditions. Animals were regularly monitored and e.uthanasiá of animals was allowed by the protocol for animals determined to be experiencing more than momentary or slight pain or distress.

6. What, if any federal regulations require this procedure?

None. However, data may be used for future registration with the EPA.

Column E Explanation QA 1941, FY12

1. Registration Number: 84-F-0001

2. Number of animals used in this study during this reporting period:

Of the 50 voles exposed, 39 were determined to have experienced more than momentary or slight pain or distress.

3. Species (common name) of animals used in study:

Voles

4. Explain procedure producing pain and/or distress:

Animals were exposed to an experimental toxicant in order to determine efficacy results for this species with a developmental toxicant.

5. Provide scientific justification why pain or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

Sedatives, analgesics, or anesthetics could not be used because the animal must be functioning normally (metabolically and physiologically) when exposed so its efficacy can be determined under more or less normal conditions. Other substances in the animals' systems could confound the results of the study and lead to a false impressions of this compound. Euthanasia of animals was allowed by the protocol for animals determined to be experiencing more than momentary or slight pain or distress.

6. What, if any federal regulations require this procedure?

No regulations specifically required this study.

However, the proposed study followed the published EPA requirements cited above for determining acute toxicity to wild animals: EPA. 2002. Health effects test guidelines OPPTS 870.1100: Acute Oral Toxicity. EPA 712-C-02-190. US EPA, Washington, D.C. We also used the guidelines referred to in the EPA document for conditions suggesting the need for a humane endpoint in studies: OECD. 2000. Guidance document on the recognition, assessment, and use of clinical signs as humane endpoints for experimental animals used in safety evaluation. ENV/JM/MONO(2000)7. OECD, Paris, France. 39 pp.

Column E Explanation QA 2007, FY12

1. Registration Number: 84-F-0001

2. Number of animals used in this study during this reporting period:

Of the 70 house mice exposed, 49 were determined to have experienced more than momentary or slight pain or distress.

3. Species (common name) of animals used in study:

House mouse

4. Explain procedure producing pain and/or distress:

Animals were exposed to registered anticoagulant toxicants combined with a substance believed to have a synergistic effect to validate those effects in this particular species.

5. Provide scientific justification why pain or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

Sedatives, analgesics, or anesthetics could not be used because the animal must be functioning normally (metabolically and physiologically) when exposed so its efficacy can be determined under more or less normal conditions. Other substances in the animals' systems could confound the results of the study and lead to a false determination of the efficacy of this compound. Euthanasia of animals was allowed by the protocol for animals determined to be experiencing more than momentary or slight pain or distress.

6. What, if any federal regulations require this procedure?

Although no regulations specifically required this study, the data could be used for registration purposes and the study was conducted in accordance with current guidance from regulatory authorities.

Agency: US Environmental Protection Agency

CFR: 40 CFR Chapter 1, Part 158: Data Requirements for Registration of Pesticide Products.

Also: U.S. EPA 2002 Humane practices for acute oral toxicity studies which include the recommendation to follow the guidelines published by the OECD (2000)